**STATEMENT OF**

**DR. ANNA JOHNSON-WINEGAR**

**DEPUTY ASSISTANT TO THE SECRETARY OF DEFENSE**

**FOR CHEMICAL/BIOLOGICAL DEFENSE**

**DEPARTMENT OF DEFENSE**

**ANTI-BIOLOGICAL WAREFARE AGENT**

**VACCINE ACQUISITION PROGRAM**

**ON**

**APRIL 14, 2000**

**BEFORE THE**

**SUBCOMMITTEE ON PERSONNEL**

**SENATE ARMED SERVICES COMMITTEE**

**FIELD HEARING AT PINE BLUFF ARSENEL, ARKANSAS**

## I. Introduction

Good afternoon, Mr. Chairman and distinguished members. I am honored to appear before your committee today to discuss the capacity of the civilian pharmaceutical industry to manufacture and supply vaccines to protect against bioterrorism and bioweapons. I am Dr. Anna Johnson-Winegar, Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense, and I am accompanied today by MG John Doesburg, Commanding General of Soldier Biological and Chemical Command. At your request, my testimony will specifically address the Biological Defense Joint Vaccine Acquisition Program (JVAP).

## II. The Biological Threat

The biological weapons threat is serious and potentially increasing in diversity and frequency. Currently, there are over 10 countries with known or suspected biological weapons programs. In addition, there are a number of non-national groups with access to such weapons. Assessing the threat is complicated by several interrelated changes, including the proliferation of weapons, technological advances, unstable political regimes, shifting regional power balances, and the increasing threat of terrorism. The threat will be exacerbated with continued and more frequent deployment of U.S. forces worldwide. The countries that are of greatest concern to the United States are located in regions in which the U. S. has well defined national security interests. Therefore, it is of paramount importance that we continue to maintain a credible, robust capability to protect our forces and provide them capabilities to operate effectively in a biologically contaminated environment.

The Department of Defense's (DoD) biological defense program is threat-driven, not technology-driven. This is because the products created by the program are for defensive purposes. The biological threat motivates the user to identify requirements and the capability needed, which, in turn, forms the basis for requirements for the research and acquisition community. The requirements are therefore generated to meet user identified materiel shortcomings. Vaccines are the most effective and least costly medical protection from biological agents and there has been significant progress within the area of biological defense vaccine policy and development. The DoD has established policy, responsibilities, and procedures for stockpiling biological agent vaccines and determined which personnel should be immunized and when the vaccines should be administered. The DoD has also identified biological agents that constitute critical threats and determined the amount of vaccine that should be stocked for each threat.

## III. History and Chronology of the Biological Defense Vaccine Program

During Operation Desert Shield/Storm (ODSS) the enemy threat posed by Iraq

created an immediate requirement for vaccines against biological warfare agents (BD vaccines), specifically anthrax and botulinum vaccines. The Anthrax Vaccine Adsorbed (AVA) is the only BD vaccine licensed by the U.S. Food and Drug Administration (FDA). The DoD recognizes the FDA licensure as the standard that determines if a vaccine is pure, safe, and effective for its intended use. Under its regulations as promulgated in Title 21 of the Code of Federal Regulations (CFR), the FDA licenses both the biologic production and storage establishments. Only the FDA Commissioner may waive the regulatory requirements of Title 21 of the CFR.

AVA is produced by BioPort Corporation of Lansing, Michigan, which is the only FDA licensed establishment for the production, testing and storage of Anthrax Vaccine Adsorbed. BioPort's facility has been licensed to manufacture the anthrax vaccine since 1970. The facilities and operations of BioPort were previously owned by the State of Michigan under the Michigan Department of Public Health until the passage of State of Michigan Public Act in December of 1996 (and amended in 1998) requiring privatization through sale. A temporary organization, the Michigan Biologics Products Institute, operated the facilities until the finalized sale to BioPort in September of 1998.

The Center for Biologics Evaluation and Research of the FDA lists 16 licensed vaccine establishments. Nine have primary facilities in the United States. Despite a large national pharmaceutical-manufacturing base in the U.S., there was little interest by U.S. commercial firms in producing biological defense products, including the AVA, for the DoD for several reasons. First, major pharmaceutical firms typically expect their products to produce in excess of $200 million in annual sales. At most, DoD will provide a small piece of this revenue expectation.

Second, the AVA vaccine places limits on the manufacturing infrastructure. As AVA utilizes a spore-bearing organism fermentation process, Title 21 CFR, Sections 600.10 and 600.11, require all capital facilities, to include production equipment and buildings associated with spore-bearing production, to be solely dedicated to the production of that one item. This adversely affects capital costs and severely limits alternative investment options since the equipment and facility can never be used to produce any other product in the future.

Third, there are concerns by U.S. commercial pharmaceutical firms that supporting DoD in this business area is inherently high risk because of changing requirements and inconsistent support for programs. Therefore, the manufacturer cannot predict quantities and schedules.

Fourth, the Biological and Toxin Weapons Convention of 1973 that addresses the issue of biological weapons has potential implications for commercial manufacturers of BD vaccines. Under the terms of a monitoring and compliance Protocol that is now being negotiated for that Treaty, it is possible that international inspectors may occasionally visit vaccine production facilities. The United States government is committed to ensuring that provisions be included in any such Protocol that assure that any visited facility will be able to protect proprietary information from disclosure during such a visit. However, commercial companies have expressed concerns that proprietary information unrelated to the BD vaccine manufacturing process might be disclosed, and they are generally leery of hosting outside inspectors. There would be less concern about such disclosure if the facility were government-owned, since the contractor operator would not be undertaking activities that were unrelated to BD vaccine manufacturing.

Several studies were conducted to examine the commercial capabilities to produce biological defense vaccines and to develop options for short and long-term production. These studies assessed whether a dedicated Government Owned/Contractor Operated (GOCO) or Contractor Owned/Contractor Operated (COCO) facility should be constructed to provide the additional capacity. Each option has advantages and disadvantages associated with production, operating costs, licensure requirements, staffing, and management. Representatives from the pharmaceutical industry, academia, and not-for-profit organizations discussed these issues of concern. Discussions led by representatives from the Food and Drug Administration (FDA) and the Pharmaceutical Research and Manufacturers Association revealed that the required production capacity was limited for BD vaccines, with current Good Manufacturing Practices (cGMP) and other regulatory compliance issues. Central to their concerns was the reality that producing BD vaccines for DoD is high risk due to issues of liability and licensure, and would require compensation for and/or protection from these risks. In addition, the FDA normally requires vaccine developers to demonstrate the safety and efficacy of each

vaccine in human clinical trials. For BD vaccines, safety can be established. However, since it is unethical to deliberately expose people to biological warfare (BW) agents, efficacy in humans can only be inferred from animal studies since there is no or limited naturally occurring disease in human populations.

Despite the initial recommendation that a dedicated production facility should be established to produce BD vaccines, the senior leadership in DoD and Congress were not convinced of the need for a dedicated facility or the most cost-effective approach. A Vaccine Production Facility Task Force worked with the Joint Staff to validate the vaccine requirement and propose alternate solutions. The U.S. Army Medical Research and Development Command requested support from the U.S. Army Health Facility Planning Agency (HFPA) at the Office of the Surgeon General to plan and construct a GOCO vaccine production facility and money was placed in the President's Budget for design and construction. In December 1993, the MILCON planning effort was suspended pending completion of a cost and feasibility study on other alternatives for acquiring BD vaccines. In 1994 the Joint Program Office for Biological Defense was chartered and part of their responsibility was to ensure DoD had an adequate vaccine acquisition capability. A cost/benefit analysis in 1994 concluded that a COCO approach was the most cost-effective, particularly if existing facilities could be used or renovated for production. In 1995, a draft Request for Proposal (RFP) for BD vaccine production was released for comment. Responses indicated that industry was more concerned with the legal and regulatory processes associated with these unique medical products rather than the production capacity issue. Four companies expressed an interest in the actual production of BD vaccines.

Based on industry responses and the economic study, a revised acquisition strategy was developed. After evaluating several options, the DoD approved the Joint Vaccine Acquisition Program (JVAP), which relies on a prime systems contractor to integrate all of the processes associated with developing, licensing, producing, storing, testing and conducting post-marketing surveillance of medical BD products. Subcontracting is accomplished on an as-needed basis. The contractor serves as the responsible agent to the FDA for product licensure. The JVAP provides government oversight of the contractor to the Joint Program Office for Biological Defense (JPO-BD).

DoD awarded a prime systems contract to DynPort LLC in November 1997. This contract begins with the development and licensure of three vaccines: Q fever, tularemia, and vaccinia, and the storage of the current stockpile of investigational BD vaccines. The contract includes options for the development and licensure of ten other BD vaccines, to include a next generation anthrax vaccine, which are programmed for development and licensure by FY 2010.

## IV. **Future recommendations**

There are multiple risks associated with having a sole-source commercial BD vaccine production facility. The DoD needs a mechanism for maximum flexibility for each vaccine product and not be locked into a contract with specific deliverables and specific production rates. As the threat changes, there may be a need to respond quickly and provide for a rapid surge capacity to meet increased production requirements for U. S. military personnel and, potentially, our domestic partners, such as the Department of State, or other essential DoD civilian and contractor personnel in a high-threat area. While there is currently no policy for the use of BD vaccines in these individuals, the possibility exists that additional requirements may be addressed at a future time, thereby increasing the number of doses required.

The Department of Defense continues to explore alternatives for vaccine production capabilities. We recognize the need to update the information on manufacturing interest of BD vaccines from the commercial sector, as well as revalidating the threat list and our capability to meet our requirements. Any decision to establish a Department of Defense alternative vaccine production facility must consider multiple factors, including the economic cost benefit analysis of a GOCO in comparison to commercial vaccine manufacturing companies. The site selection would be based on a best value determination considering a number of factors. Availability of a secure siting location, adequacy of available workforce in the area, linkage to a technical community suitable to support the facility, cost of construction and operation, existing infrastructure such as power, water, sewer and roads, and compatibility of other on-going installation missions are some of the factors that would influence the best value determination. Upon

site selection, a full and open contracting process would be utilized to design, construct and operate the facility.